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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,328	07/18/2003	Stefanic Lattner	98-15 DI	3272
30031	7590	09/28/2007		
MICHAEL W. HAAS RESPIRONICS, INC. 1010 MURRY RIDGE LANE MURRYSVILLE, PA 15668			EXAMINER THOMAS, JONATHAN B	
			ART UNIT	PAPER NUMBER
			3709	
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			09/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/623,328

Applicant(s)

LATTNER ET AL.

Examiner

Jonathan B. Thomas

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43-58 and 60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43-58, 60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

Response to Arguments

Applicant's arguments of the rejection of claims 43-60, filed 9/17/2007 have been fully considered but they are not persuasive.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, as per applicant's own disclosure, prior art non-invasive stimulation techniques, including the one disclosed in Meer, did not successfully treat a sufficient number of patients. It would have been obvious to a person having ordinary skill in the art to combine the

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partly effective treatment regime with a previously known technique such as mandible positioning in order to increase efficacy. This technique is common in the medical arts as is demonstrated by the use of both aspirin and acetaminophen to fight pain in combination pain relievers such as Excedrin. The rejection of claims 43-56 stands as originally written.

It is noted that the applicant makes reference to claim 1 in their arguments. Claim 1 is not pending in this prosecution. It has been interpreted that the applicant has made reference their first pending claim, claim 43 in all places where claim 1 is mentioned.

It is further noted that the applicant's treatment of sleep apnea syndrome with an optimal combination of prior art devices (jaw positioning and non-implantable stimulation) does not affect the obviousness of the combination. It would have been reasonable for a person having ordinary skill in the art to discover the claimed invention during the course of routine experimentation. All of the components of the invention were known in the prior art. The only difference between the claimed invention and the prior art is the combination of pre-existing elements into a single device.

Regarding the rejection of claims 57-60 also stands as originally written. The positioning of stimulation electrodes relative to one another is a quantifiable property and subject to the rulings *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) MPEP 2144.05 II A.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 43-47 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meer 5,190,053 in view of Halstrom 5,365,945.

Meer teaches the electromuscular stimulating means 10, electrode positioning means 24, respiration detecting means and means for controlling a delivery of electrical energy (Col. 2 ll. 56-66), however Meer does not teach the following claimed limitations taught by Halstrom: Mandibular positing means 20 and members adapted to engage a structure associated with a patient's upper dentition and mandible and means for limiting the movement of one relative to the other 28, 32, and 40 respectively. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the Meer apparatus in view of Halstrom in order to maintain the patient's mandible in a protruded position, thereby averting obstruction of the pharyngeal pathway (Col. 4 ll. 20-24).

Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meer in view of Halstrom as applied to claims 43-47, and 49 above, and further in view of Durkan 4,414,982.

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Meer and Halstrom teach the apparatus described above, however they do not teach the following limitation taught by Durkan: Means for providing a positive pressure to an airway 22. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the Meer and Halstrom apparatus as described above with the airway of Durkan to supply oxygen to a patient substantially throughout the duration of an inspiration (Col. 1 ll. 36-39).

Method claims 50-54, and 56 are rejected because the apparatus of Meer in view of Halstrom as applied to claims 43-47, and 49 above performs the method steps as claimed.

Method claim 55 is rejected because the apparatus of Meer in view of Halstrom in view of Durkan as applied to claim 48 above performs the method steps as claimed.

Claims 57, 58, and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meer in view of *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Meer teaches the first and second electrodes 12, first and second support members 24, respiratory sensor (Col. 2 ll. 56-66), stimulation through at least a portion of inspiration (Col. 6 ll. 44-47), and support member coupling 18 and 20, but it does not teach the following claimed limitations: posterior to anterior or anterior to posterior electrode placement and stimulation nor stimulation start time prior to onset of inspiration. However it has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)

MPEP 2144.05 II A.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan B. Thomas whose telephone number is (571)270-3082. The examiner can normally be reached on Mon-Fri 7:30-5 EST. Alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ehud Gartenberg can be reached on 5712724868. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

9/26/2007


KIMBERLY S. SMITH
PRIMARY EXAMINER

9/26/07